K002499

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NOV - 8 2000

Section 14: 510(k) Summary

Brentwood IQmark™ Digital Spirometer

1. ***Manufacturer/Applicant***:
   Brentwood Medical Technology Corporation
   3300 Fujita Street
   Torrance, CA 90505
   Attn: Glen Mizelle, Product Manager
   Phone: 310-530-5955
   Fax: 310-530-1421
   Summary Preparation Date: June 27, 2000

2. ***Proprietary Name***: Brentwood IQmark™ Digital Spirometer
   Common/Usual Name: Spirometer
   Classification Name: Diagnostic Spirometer
   Classification Panel: Anesthesiology
   Classification Code: BZG

3. ***Substantial Equivalence***: The Brentwood IQmark™ Digital Spirometer is substantially equivalent to the Spirometrics Medical Equipment Company PC-Flow+ Spirometer (submitted to FDA as the Serial Flow K900673); the Futuremed America, Inc., Spirovision SV-III PC Based Spirometer Kit Micro (K953948); and the Mallinckrodt Puritan-Bennett Renaissance Spirometry System (K944762).

4. ***General Device Description***: Figure 1 presents a block diagram of the Brentwood IQmark™ Digital Spirometer system. The product consists of a polypropylene plastic Disposable Pneumotach Mouthpiece, an insulated plastic sensor handle that connects to a Windows based Personal Computer (PC) via an RS-232C serial cable connection, and software that runs the diagnostic spirometer application on the PC.

   The sensor handle contains two series AAA batteries (1.5v) and sensor electronics for measuring pressure differences caused by air flow through the Disposable Pneumotach Mouthpiece. The Disposable Pneumotach Mouthpiece snaps onto the sensor handle. This is a hollow tube with laminar flow elements molded into its middle; it has one self-sealing pressure tap on each side of its laminar flow elements for connection to the pressure transducer located in the sensor handle. The patient inserts one end of the Disposable Pneumotach Mouthpiece into his or her mouth and performs various breathing maneuvers depending upon the type of diagnostic spirometry test being performed.

   The sensor handle measures the pressure differential caused by bi-directional air flow through the flow tube, converts the pressure signal into digital samples and sends the digitized sample points to the PC via a serial cable. The software runs on a Windows 95 (or 98 or 2000 Professional) or Windows NT (version 3.51 or later) personal computer operating

system. This software reads the digitized pressure data and calculates flow. From the flow data, the software calculates volume and flow-volume measurements for Forced Vital Capacity, Vital Capacity, and Maximal Voluntary Ventilation tests. The software interacts with the operator via several operator screens and dialog boxes to step the operator through the procedure of performing these tests. Upon completion of the tests, the software allows the operator to review, edit, and print pulmonary function test reports.

The device includes the following accessories that are purchased separately:

1. Disposable Pneumotach Mouthpieces
2. 3-Liter Calibration Syringe

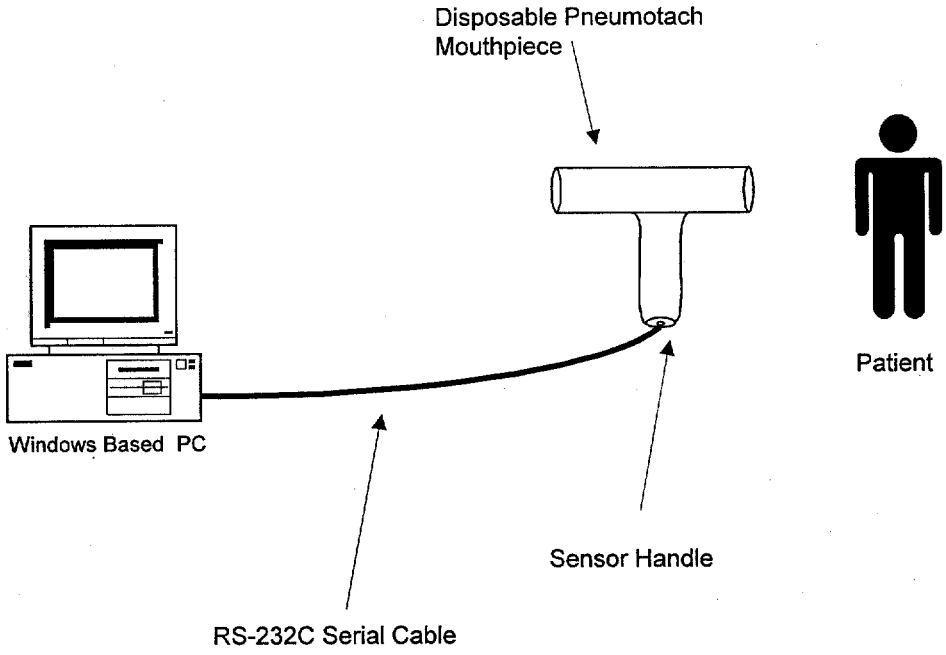

Figure 1: Brentwood IQmark™ Digital Spirometer System Block Diagram

5. ***Intended Use, Indications for Use, & Environment***:

Intended Use: The Brentwood IQmark™ Digital Spirometer is intended for use as a prescription-use-only clinical diagnostic spirometer for pulmonary function evaluation and data management.

Environment of Use: The Brentwood IQmark™ Digital Spirometer is for use in hospitals and physician/clinician offices by individuals that have received minimal instruction or training in the administration of spirometry tests. The Spirometer operates with an IBM PC compatible computer using a serial port connection and the PC's installed Brentwood Medical Workstation Windows™ compatible software. Minimum PC and operating system requirements are specified in the Operator's Manual.

Indications for Use: The Brentwood IQmark™ Digital Spirometer is indicated for use with male/female adult patients and male/female pediatric patients to evaluate, assess, describe, measure, or monitor:

1. symptoms, signs, or abnormal laboratory tests
2. effects of disease on pulmonary function
3. individuals at risk for pulmonary disease
4. preoperative risk
5. post-surgical prognosis
6. pre-treatment health status
7. therapeutic interventions
8. the course of disease affecting lung function
9. persons exposed to pollutants
10. adverse reactions to drugs with known pulmonary toxicity
11. rehabilitation programs
12. risks as part of an insurance evaluation
13. individuals for legal reasons
14. epidemiological surveys
15. derivation of reference equations

Contraindications: The Disposable Pneumotach Mouthpieces are clean but are not sterile and should not be placed over open wounds that are prone to infection. There are no other known medical contraindications other than the physical limitations of the patient.

Complications: The Brentwood IQmark™ Digital Spirometer is a non-invasive device and is safe in both construction and use. This has been confirmed by the performance of Verification and Validation Testing, Biocompatibility Testing, Risk Assessment Analysis, and ATS testing. Following are some possible minor complications that occur with <u>all</u> diagnostic spirometers:

1. infection or further injury due to use of nonsterile mouthpiece over open wounds
2. skin or mucous membrane abrasion after prolonged or excessive use caused by rubbing of mouthpiece (not related to biocompatibility issues)
3. nasal, oral, or dental pain
4. drying of oral or pharyngeal mucosa
5. congestion or irritation of eustachian tubes
6. gastric distention or flatulence from ingested air
7. some slight discomfort during test procedures
8. decreased secretion clearance during test procedures
9. aspiration of secretions
10. hyperventilation and possible dizziness

6. ***Comparison to Predicates:*** The characteristics of the Brentwood IQmark™ Digital Spirometer are similar to those of the predicates mentioned in item # 3 above. The few minor differences in technological characteristics do not raise any new questions regarding safety or effectiveness. Refer to Comparison Chart on next two pages.

		Predicate Devices			Brentwood IQmark™ Digital Spirometer
#	Characteristic	Spirometrics PC-Flow+	Futuremed Spirovision SV-III	Mallinckrodt Puritan-Bennett Renaissance System	Similar To At Least One Predicate
1	PC Based	yes	yes	no	yes
2	physical configuration	pneumotach with handle (containing electronics) that connects directly to PC serial port via cable; system software disk for PC installation	pneumotach with handle (containing electronics) that connects directly to PC serial port via cable; system software disk for PC installation	hand-held disposable pneumotach mouthpiece connects to spirometer electronics via pneumatic line; base station charges spirometer battery, interfaces to printer & PC; patient data memory card interfaces to spirometer electronics or base station	Disposable Pneumotach Mouthpiece with handle (containing electronics) that connects directly to PC serial port via cable; system software disk for PC installation
3	minimum PC requirements	DX2-50 processor; 8 Mb RAM; Windows™ 3.1X, 95, 98 or NT Workstation; Windows compatible printer	486 DX 66MHz processor; 8 Mb RAM; Windows™ 3.1, 95, 98 or NT; 10 MB HD space; Windows compatible printer	80386 processor; 4 Mb RAM; Windows™ 3.1, 95, 98 or NT; 2.5 MB HD space; Windows compatible printer	Pentium 100 MHz processor; 16Mb RAM (Windows 95 & 98), 32 Mb RAM (Windows NT), 64 Mb RAM (Windows 2000 Professional); 10 MB HD space; Windows compatible printer
4	power source	pneumotach with handle: from host computer, 8 volts @ 5 ma	pneumotach with handle: 4 series batteries (1.5v AAA) inside handle	spirometer electronics: 3.6v rechargeable NiCad battery pack	Disposable Pneumotach Mouthpiece with handle: two series AAA batteries (1.5v) inside handle
5	ATS spirometry performance recommendations	complies	complies (1994 Update)	complies (1994 Update)	complies (1994 Update)
6	cross-contamination control	disposable mouthpieces, external filters, cold disinfection of pneumotach	disposable mouthpieces, external filters, sensor insert cold-sterilized	disposable pneumotach mouthpieces	Disposable Pneumotach Mouthpieces
7	flow detection principle	reusable pressure differential measuring pneumotach	reusable bi-directional digital turbine	disposable pressure differential measuring pneumotach mouthpieces for expiratory testing (unidirectional) & for expiratory / inspiratory testing (bi-directional)	disposable bi-directional pressure differential measuring pneumotach mouthpieces for expiratory/inspiratory testing
8	flowmeter calibration method	injection of known fixed volume from calibrated syringe	injection of known fixed volume from calibrated syringe	injection of known fixed volume from calibrated syringe	injection of known fixed volume from calibrated syringe

		Predicate Devices			Brentwood IQmark™ Digital Spirometer
#	Characteristic	Spirometrics PC-Flow+	Futuremed Spirovision SV-III	Mallinckrodt Puritan-Bennett Renaissance System	Similar To At Least One Predicate
9	display & printer used	PC monitor screen (CRT) and PC printer	PC monitor screen (CRT) and PC printer	spirometer LCD display; Centronics-compatible parallel printer port at base station; database software display/printout via PC peripherals	PC monitor screen (CRT); alpha-numerics and graphics
10	graphic output	Flow-Volume loop, Volume-Time curve, predicted curve, pre & post bronchodilator comparison	Flow-Volume loop, Volume-Time curve, superimposed graphs for comparison	no graphics on LCD; base station Flow-Volume loop & Volume-Time curve printouts; PC software provides database management only	Flow-Volume loop, Volume-Time curve, predicted curve, pre & post bronchodilator comparison
11	tests performed	FVC, F-V loops, MVV, VC (SVC), IVC, respiratory pattern, pre/post comparisons, broncho-challenge	FVC, F-V loops, MVV, VC (SVC), IVC, respiratory pattern, pre/post comparisons, broncho-challenge	FVC, F-V loops, MVV, VC (SVC), IVC	FVC, F-V loops, MVV, VC (SVC), IVC, respiratory pattern, pre/post comparisons, broncho-challenge
12	indices calculated (bold text indicates that an index used by Brentwood Spirometer is also used by a listed predicate)	**FVC; FEV_1; FEV_3; FEV_1/FVC; $FEF_{25-75\%}$; $FEF_{75-85\%}$; FEF_{25}; FEF_{50}; FEF_{75}; $FEF_{200-1200}$; PEF; FIVC; FIF_{50}; FIF_{50}/FEF_{50}; PIF;** COPD (risk assessment); Lung Age; **MVV Volume & Rate; VC;** ATI (air trapping index); PD20 (provocative dose)	**FVC; FEV_1;** $\%FEV_1$; **FEV_3;** $FEV_3/FVC\%$; **$FEV_1/FVC\%$;** $FEV_1/VC\%$; **FEF_{25-75}; FEF_{75-85};** FEF_{25-50}; FEF_{50-75}; **PEF; IVC;** IC; **PIF; MVV; VC; V_T;** V_{max25}; V_{max50}; V_{max75}; FET100%; **ERV;** V_E; **R_f;** t_I; **t_E;** t_I/t_{tot}; V_T/t_I; FEV_2; FEV_2/FVC%	**FVC; FEV_1;** $\%FEV_1$; **FEV_3; FEF_{25-75}; PEF; FIVC; $FEF_{50\%}/FIF_{50\%}$; PIF; MVV; FET (t_E)**	**FVC;** $FEV_{0.5}$; **$FEV_{1.0}$; $FEV_{3.0}$; $FEV_{1.0}$/FVC; $FEF_{25-75\%}$; $FEF_{75-85\%}$; $FEF_{25\%}$; $FEF_{50\%}$; $FEF_{75\%}$; $FEF_{200-1200}$; PEF; FIVC; $FIF_{50\%}$; FEF_{50}/ FIF_{50}; PIF; MVV; VC; V_T; ERV; RR; t_E;** V_{ext}; $FIV_{0.5}$; $FEV_{0.5}/FIV_{0.5}$; MV_T; IRV
13	predictive models used (bold text indicates predicted model used by Brentwood Spirometer also used by predicate)	Adult: **Knudson, Crapo (ITS),** & Morris; Pediatric: Hsu	Adult: **Knudson 83**, **Crapo (ITS)**, & **ECCS** '83 (ERS **93**); Pediatric: **Knudson 83**, Crapo (ITS) & Zapletal	Adult: **Knudson 76 & 83**, **Crapo (ITS)**, & Morris 71; Pediatric: **Polgar** & Hsu	Adult: **Knudson 76 & 83, Crapo (ITS), ECCS 93** Pediatric: **Polgar** 71 and **Knudson** 76 & **83**

K041171

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2000

Mr. Glen Mizelle
Brentwood Medical Technology Corporation
3300 Fujita Street
Torrance, CA 90505

Re: K002499
Brentwood IQmark™ Digital Spirometer
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: August 11, 2000
Received: August 14, 2000

Dear Mr. Mizelle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002499

SECTION 5: INDICATIONS FOR USE STATEMENT

510(k) Number (if known) Unknown At This Time

Device Name: Brentwood IQmark™ Digital Spirometer (Includes Single-Patient Use Disposable Pneumotach Mouthpieces and 3-Liter Calibration Syringe)

Indications For Use:

The Brentwood IQmark™ Digital Spirometer is intended for use as a prescription-use-only clinical diagnostic spirometer for pulmonary function evaluation and data management.

The Spirometer is for use in hospitals and physician/clinician offices by individuals that have received minimal instruction or training in the administration of spirometry tests. The Spirometer operates with an IBM PC compatible computer using a serial port connection and the PC's installed Brentwood Medical Workstation Windows™ compatible software. Minimum PC and operating system requirements are specified in the Operation Manual.

The Spirometer is indicated for use with male/female adult patients ~~and male/female pediatric~~ patients to evaluate, assess, describe, measure, or monitor:

1. symptoms, signs, or abnormal laboratory tests
2. effects of disease on pulmonary function
3. individuals at risk for pulmonary disease
4. preoperative risk
5. post-surgical prognosis
6. pre-treatment health status
7. therapeutic interventions
8. the course of disease affecting lung function
9. persons exposed to pollutants
10. adverse reactions to drugs with known pulmonary toxicity
11. rehabilitation programs
12. risks as part of an insurance evaluation
13. individuals for legal reasons
14. epidemiological surveys
15. derivation of reference equations

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, ~~and Neurological~~ Devices
510(k) Number K002499

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)